

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SEP 06 2005
 OIPE 14078
 SEP 06 2005
 In re application of: Osorio et al.
 Serial No.: 10/783,723
 Filed: 20 February 2004
 For: Methods and Devices for Treating Fractured and/or Diseased Bone

Group Art Unit: <
 Examiner: <

Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT WITHIN
 THREE MONTHS OF FILING OR BEFORE MAILING OF FIRST OFFICE ACTION
 (37 CFR 1.97(b))**

NOTE: "An information disclosure statement shall be considered by the Office if filed: (1) within three months of the filing date of a national application; (2) within three months of the date of entry of the national stage as set forth in S 1.491 in an international application; or (3) before the mailing date of a first Office action on the merits, whichever event occurs last." 37 CFR 1.97(b).

NOTE: The "filing date of a national application" under 37 CFR 1.97(b) has two possible meanings. Where the filing is a direct one to the United States Patent & Trademark Office, the filing is defined in 37 CFR 1.53(b) as "the date on which: (1) A specification containing a description pursuant to S 1.71 and at least one claim pursuant to S 1.75; and (2) any drawing required by S 1.81(a), are filed in the Patent and Trademark Office in the name of the actual inventor or inventors as required by S 1.41." 37 CFR 1.97(b)(1). On the other hand, an international application that enters the national stage occurs when the applicant has filed the documents and fees required by 35 U.S.C. S 371(c) within the periods set forth in S 1.494 or S 1.495. 35 U.S.C. S 371(c) requires the filing of the following: (1) the national fee; (2) a copy of the international application, unless already sent by the International Bureau, and an English translation if filed in another language; (3) amendments under PCT Article 19, with a translation into English if made in another language; (4) an oath or declaration; and (5) a translation into English of any annexes to the international preliminary examination report, if such annexes were made in another language. 37 CFR 1.97(b)(2).

**IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING INFORMATION
 DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed WITHIN THREE MONTHS OF THE FILING DATE OF THE APPLICATION OR DATE OF ENTRY INTO THE NATIONAL STAGE OF AN INTERNATIONAL APPLICATION OR BEFORE THE MAILING DATE OF A FIRST OFFICE ACTION ON THE MERITS, WHICHEVER EVENT OCCURS LAST. 37 CFR 1.97(b).

NOTE "NO CERTIFICATION OR FEE IS DUE WHEN THE FILING IS MADE WITHIN THE ABOVE TIME PERIOD. IT IS ADVISABLE TO ENSURE THAT NO OFFICE ACTION HAS BEEN MAILED IF THE DISCLOSURE STATEMENT IS DELAYED UNTIL AFTER THREE MONTHS FROM FILING.

NOTE: "An information disclosure statement will be considered to have been filed on the day it was received in the Office, or on an earlier date of a mailing if accompanied by a properly executed certificate of mailing under 37 CFR 1.8, or Express Mail certificate under 37 CFR 1.10. An Office action is mailed on the date indicated in the Office action." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

CERTIFICATE OF MAILING (37 CFR 1.8(a)) or (37 CFR 1.10)

I hereby certify that this paper (along with any referred to as being attached or enclosed) is being deposited with the United State Postal Service on the date shown below as First Class Mail in an envelope addressed as follows: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450

Mary Szolar
 Type or print name of person mailing paper

Date: 2 September 2005

Mary Szolar
 (Signature of person mailing paper)

NOTE: "The term 'national application' includes continuing applications (continuations, divisions, continuations-in-part) so three-months will be measured from the actual filing date of an application as opposed [sic] to the effective date of a continuing application." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "An action on the merits means an action which treats the patentability of the claims in an application, as opposed to only formal or procedural requirements. An action on the merits would, for example, contain a rejection or indication of allowability of a claim or claims rather than just a restriction requirements (37 CFR 1.142) or just a requirement for additional fees to have a claim considered (37 CFR 1.16(d)). Thus, if an application was filed on Jan. 1 and the first Office action on the merits was not mailed until six months later on July 1, the examiner would be required to consider any proper information disclosure statement filed prior to July 1." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

WARNING: "A PETITION FOR SUSPENSION OF ACTION TO ALLOW APPLICANT TIME TO SUBMIT AN INFORMATION DISCLOSURE STATEMENT WILL BE DENIED AS FAILING TO PRESENT GOOD AND SUFFICIENT REASONS, SINCE 37 CFR 1.97 PROVIDES ADEQUATE RECOURSE FOR THE TIMELY SUBMISSION OF PRIOR ART FOR CONSIDERATION BY THE EXAMINER." NOTICE OF JULY 6, 1992 (1141 O.G. 63).

The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* prior art reference against the claims of the present application.

Should any fees be necessary in connection with this submission, please charge same to Account No. 06-2360.

Date 2 September 2005



Reg. No. 29,243

Signature of Attorney of Record

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LIST OF PRIOR ART CITED BY APPLICANT
(Use several sheets if necessary)ATTY DOCKET NO.
1759.17207-FOR DIV 2SERIAL NO.
10/783,723APPLICANT
Osorio et al.

CUSTOMER NO. 26308

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U.S. PATENT DOCUMENTS

DOCUMENT NUMBER	Date	Name	Class	Subclass	Filing Date (If Appropriate)
1,965,653	10 Jul 34	Kennedy			
3,049,125	14 Aug 62	Krikkowitsch			
3,091,237	28 May 63	Skinner			
3,112,743	3 Dec 63	Cochran et al.			
3,626,949	14 Dec 71	Shute			
3,648,294	14 Mar 72	Shahrestani			
3,766,924	23 Oct 73	Pidgeon			
3,779,241	18 Dec 73	Vennard et al.			
3,800,788	2 Apr 74	White			
3,850,176	26 Nov 74	Gottschalk			
3,875,595	8 Apr 75	Froning			
3,889,665	17 Jun 75	Ling et al.			
3,997,138	14 Dec 76	Crock et al.			
4,018,230	19 Apr 77	Ochiai et al.			
4,083,369	11 Apr 78	Sinnreich			
4,274,163	23 Jun 81	Malcom et al.			
4,313,434	2 Feb 82	Segal			
4,367,816	11 Jan 83	Wilkes			
4,369,772	25 Jan 83	Miller			
4,399,814	23 Aug 83	Pratt, Jr. et al.			
4,432,358	21 Feb 84	Fixel			
4,462,394	31 Jul 84	Jacobs			
4,466,435	21 Aug 84	Murray			
4,467,479	28 Aug 84	Brody			

EXAMINER

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	APPLICANT Osorio et al.	
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U.S. PATENT DOCUMENTS

Examiner Initial	DOCUMENT NUMBER	Date	Name	Class	Subclass	Filing Date (If Appropriate)
	4,488,549	18 Dec 84	Lee et al.			
	4,562,598	7 Jan 86	Kranz			
	4,595,006	17 Jun 86	Burke et al.			
	4,625,722	2 Dec 86	Murray			
	4,627,434	9 Dec 86	Murray			
	4,628,945	16 Dec 86	Johnson, Jr.			
	4,637,396	20 Jan 87	Cook			
	4,653,489	31 Mar 87	Tronzo			
	4,685,447	11 Aug 87	Iversen et al.			
	4,686,973	18 Aug 87	Frisch			
	4,697,584	6 Oct 87	Haynes			
	4,706,670	17 Nov 87	Andersen et al.			
	4,714,478	22 Dec 87	Fischer			
	4,772,287	20 Sep 88	Ray et al.			
	4,878,495	7 Nov 89	Grayzel			
	4,888,022	19 Dec 89	Huebsch			
	4,888,024	19 Dec 89	Powlan			
	4,892,550	9 Jan 90	Huebsch			
	4,896,662	30 Jan 90	Noble			
	4,909,252	20 Mar 90	Goldberger			
	4,932,975	12 Jun 90	Main et al.			
	4,969,888	13 Nov 90	Scholten et al.			

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Examiner Initial	DOCUMENT NUMBER	Date	Name	Class	Subclass	Filing Date (If Appropriate)
	4,987,892	29 Jan 91	Krag et al.			
	5,002,576	26 Mar 91	Fuhrmann et al.			
	5,015,255	14 May 91	Kuslich)		
	5,049,132	17 Sep 91	Shaffer et al.			
	5,053,035	1 Oct 91	McLaren			
	5,062,845	5 Nov 91	Kuslich et al.			
	5,071,435	10 Dec 91	Fuchs et al.			
	5,102,413	7 Apr 92	Poddar			
	5,108,404	28 Apr 92	Scholten et al.			
	5,127,912	7 Jul 92	Ray et al.			
	5,137,512	11 Aug 92	Burns et al.			
	5,147,366	15 Sep 92	Arroyo et al.			
	5,163,949	17 Nov 92	Bonutti			
	5,163,989	17 Nov 92	Campbell et al.			
	5,176,638	5 Jan 93	Don Michael			
	5,176,683	5 Jan 93	Kimsey et al.			
	5,176,692	5 Jan 93	Wilk et al.			
	5,290,306	1 Mar 94	Trotta et al.			
	5,295,994	22 Mar 94	Bonutti			
	5,303,718	19 Apr 94	Krajicek			
	5,330,429	19 Jul 94	Noguchi et al.			
	5,331,975	26 Jul 94	Bonutti			

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U.S. PATENT DOCUMENTS

Examiner Initial	DOCUMENT NUMBER	Date	Name	Class	Subclass	Filing Date (If Appropriate)
	5,361,752	8 Nov 94	Moll et al.			
	5,383,932	24 Jan 95	Wilson et al.			
	5,423,850	13 Jun 95	Berger			
	5,425,710	20 Jun 95	Khair et al.			
	5,441,538	15 Aug 95	Bonutti			
	5,445,639	29 Aug 95	Kuslich et al.			
	5,454,365	3 Oct 95	Bonutti			
	5,468,245	21 Nov 95	Vargas, III			
	5,480,400	2 Jan 96	Berger			
	5,514,143	7 May 96	Bonutti et al.			
	5,514,153	7 May 96	Bonutti			
	5,522,790	4 Jun 96	Moll et al.			
	5,522,846	4 Jun 96	Bonutti			
	5,527,343	18 Jun 96	Bonutti			
	5,527,624	18 Jun 96	Higgins et al.			
	5,531,856	2 Jul 96	Moll et al.			
	5,540,711	30 Jul 96	Kieturakis et al.			
	5,545,222	13 Aug 96	Bonutti			
	5,549,388	27 Aug 96	Wilkes			
	5,549,679	27 Aug 96	Kuslich			
	5,562,736	8 Oct 96	Ray et al.			
	5,571,109	5 Nov 96	Bertagnoli			

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U.S. PATENT DOCUMENTS

Examiner Initial	DOCUMENT NUMBER	Date	Name	Class	Subclass	Filing Date (If Appropriate)
	5,571,189	5 Nov 96	Kuslich			
	5,755,690	26 May 98	Saab			
	5,772,681	30 Jun 98	Leoni			
	5,788,703	4 Aug 98	Mittelmeier et al.			
	5,893,840	13 Apr 99	Hull et al.			
	6,017,305	25 Jan 00	Bonutti			
	6,066,154	23 May 00	Reiley et al.			
	6,235,043	22 May 01	Reiley et al.			
	6,248,110	19 Jun 01	Reiley et al.			

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	DOCUMENT NUMBER	DATE	COUNTRY	Class	Subclass	Translation Yes No
	439,636	3 May 12	Europe / Fr			
	512,456	15 Sep 39	United Kingdom			
	906,530	25 Feb 82	Russia			
	1,148,610	7 Apr 85	Russia			
	3,736,604	5 Nov 89	Germany			
	9,001,858	16 Mar 92	Netherlands			
	0 493,789	Jul 92	Europe			
	WO 95/03083	Feb 95	PCT			

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OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)

		Aebi, M., 'The Internal Skeletal Fixation System. A New Treatment of Thoracolumbar Fractures and Other Spinal Disorders', Clinical . Orthop., Vol 227, pp. 30-43 (1988)
		Blauth, M., 'Therapeutic Concept and Result of Operative Treatment in Acute Trauma of the Thoracic and Lumbar Spine: the Hannover Experience,' J. of Orthop. Trauma, Vol 1, No. 3, pp. 240-52 (1987)
		Campbells' Operative Orthopaedics, A.H. Crenshaw, Ed., 7 th ed., Chapter 44, pp. 1653-63 (1987)
		Carlson, 'The Use of Methylmethacrylate in Repair of Neoplastic Lesions in Bone,' Radiology, Vol. 112, pp. 43-46 (July 1974)
		Cohen, L., M.D., 'Fractures of the Osteoporotic Spine, Pathologic Fractures in Metabolic Bone Disease', The Orthopedic Clinics of N. America. Vol. 21:1, 1/1990, pgs. 153-152.
		Daniaux, H., 'Technik und Ergebnisse der Transpedikularen Spongiosaplastik Bei Kompressionsbrüchen im Lendenwirbelsäulenbereich' Acta Chir. Austr. (Suppl.), Vol 43, pp. 79-80 (1982) (with English Translation)
		Daniaux, H., 'Transpedikulare Reposition und erste Spongiosaplastik Bei Wirbelkörperbrüchen der Unteren Brust und Lendenwirbelsäule,' Unfallchirurg., Vol 89, pp. 197-213 (1986) (with English Translation)
		Dick, W., 'The 'Fixatuer Interne' as Versatile Implant for Spine Surgery,' Spine, Vol 12(9), pp. 882-900 (1987)
		Dick, W., 'Use of the Actebular Reamer to Harvest Autogenic Bone Graft Material: A Simple Method for Producing Bone Paste,' Arch. Orthop. Trauma Surg., Vol 105, pp. 234-38 (1986)
		Edeland, H.G., 'Open Reduction of Central Compression Fractures of the Tibia Plateau,' Acta Orthop. Scand., Vol 47, pp. 686-89 (1976)
		Harrington, K., 'The Use of Methylmethacrylate as an Adjunct in the Internal Fixation of Malignant Neoplastic Fracture', The Journal of Bone and Joint Surgery, Vol. 54A, No. 8, 12/1972; pgs. 1665-1676.
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OTHER PRIOR ART (<i>Including Author, Title, Date, Pertinent Pages, Etc.</i>)		
		Kennedy, W., "Fracture of the Tibia Condyles: A Preliminary Report of Supplementary Fixation with Methylmethacrylate," Clin. Orthop., Vol 143, pp. 153-57 (1978)
		Kunec, J.R., et al., "Closed Intramedullary Rodding of Pathologic Fractures with Supplemental Cement," Clinical Orthopaedics and Related Research, Vol. 188, pp. 183-86 (Sep. 1984)
		Ma, Yuan-zhang, "Os Calsis Fracture Treated by Percutaneous Poking Reduction and Internal Fixation," Chinese Medical J., Vol 97, No 2, pp. 105-10 (1984)
		Melton, III, et al.; "Perspective: How Many Women Have Osteoporosis", Journal of Bone and Mineral Research, Vol. 7, No. 9, 1992; pgs. 1005-1010.
		Olerud, S., "Transpedicular Fixation of Thoracolumbar Vertebral Fractures", Clin. Orthop., Vol 227, pp. 44-51 (1988)
		Pentelenyi, T., "First Hungarian Neurosurgical Experiences with 'Fixateur Interne' in the Treatment of Thoraco-Lumbar Spine Injuries," Acta Neurochir. (Wien), Vol 93, pp. 104-09 (1988)
		Riggs, B. Lawrence, M.D. et al. "Medical Progress, Involutional Osteoporosis: The New England Journal of Medicine; 6/26/86; pgs. 1676-1686.
		Schatzker, J., Operative Orthopaedics, M. Chapman, Ed., 1 st ed., Ch. 35, pp. 421-34 (1998)
		Scoville, W., "The Use of Acrylic Plastic for Vertebral Replacement or Fixation in Mestastic Disease of the Spine," J. Neurosurg., Vol. 27: 274-79 (Sept. 1967)
		Silverman, S.L., "The Clinical Consequences of Vertebral Compression Fracture", Bone, 13, S27-S31 (1992).

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